

# **FDA Public Health Notification: Illegal Promotion of Contact Lenses**

(You are encouraged to copy and distribute this Notification to contact lens users.)

September 25, 1998

To: Eyecare Practitioners Who Dispense Contact Lenses

## **Purpose of this Notification**

The Food and Drug Administration (FDA) is notifying eyecare practitioners, contact lens dispensers and contact lens wearers of two illegal and potentially unsafe practices on the part of some contact lens companies: (1) promoting the sale of tinted contact lenses that have not been evaluated by FDA for safety or effectiveness; and (2) marketing orthokeratology lenses which have not been cleared for marketing or approved as part of an investigational study by FDA. In both cases, firms have promoted the contact lenses through various media, including the Internet, professional journals and trade publications.

The color additives used in unapproved tinted lenses have not been evaluated for safety—we have no information on their identity, chemical composition, stability or potential toxicity, and we do not know whether they can cause irritation or injury to the eye. Additionally, FDA has not inspected the facilities where these lenses are made to determine whether they are in compliance with good manufacturing practices requirements.

The overnight use of orthokeratology contact lenses raises other safety concerns, since no reliable data are presently available in the literature to evaluate this technique. Persons wearing orthokeratology lenses overnight are considered to be at risk for mechanical effects on the cornea such as corneal warpage or epithelial damage that could result in infection. Although the safety risks of interrupted overnight wear may not be as great as continued overnight wear, there is still an increased risk of corneal damage beginning with the first overnight period.

**Because of these safety concerns, we are recommending that eyecare practitioners prescribe only tinted lenses that have been approved or cleared for marketing by FDA, and orthokeratology lenses that have either been cleared for marketing or approved for use as part of an investigational study by FDA. We are also cautioning contact lens dispensers and users against using the services of firms illegally marketing tinted lenses or orthokeratology lenses.**

## **Regulatory Background**

Tinted contact lenses, including plano or zero powered lenses, that are promoted for sale to the general public are medical devices that are required to undergo clearance for safety and effectiveness by FDA before they can be legally introduced or delivered into interstate commerce for commercial distribution. The same holds true for orthokeratology contact lenses, including those manufactured from rigid gas permeable (RGP) materials approved for overnight use. Daily wear lenses must receive marketing clearance through FDA's premarket notification process (510(k)), and extended wear lenses must receive marketing approval through an approved application for premarket approval (PMA).

Contact lens manufacturers and finishing labs who promote the sale of a specific orthokeratology lens design to eyecare practitioners are subject to regulation by FDA. The same regulation applies to eyecare practitioners who promote orthokeratology lenses outside the scope of their own practices—e.g., the marketing and promotion of an unapproved product to other practitioners. Companies that promote a service of tinting approved clear contact lenses for eyecare practitioners before or after the lenses have been dispensed are also subject to regulation by FDA, since these companies are changing the specifications of the approved lens.

Individual color additives used in the manufacture of tinted lenses are required to be listed in the Code of Federal Regulation (CFR) for use in contact lenses in accordance with FDA's color additive regulation. Before a color additive is listed as safe for use in coloring contact lenses, information about the additive is carefully evaluated by FDA for biocompatibility with ocular tissue. This review process effectively eliminates the use of color additives that are toxic to eye tissue and those that are carcinogens.

Although orthokeratology has been practiced since the early 1960's, there has been only one contact lens cleared for marketing by FDA for orthokeratology performed on a daily wear basis. The safety issues for most daily wear orthokeratology lenses have generally been addressed by prior research and review of the one lens cleared for marketing. FDA is not aware of any well-controlled clinical studies published in the literature on the overnight use of orthokeratology lenses. The overnight use of lenses is not considered daily wear and is considered extended wear since the lens is worn while the user is asleep.

An RGP lens designed for orthokeratology requires different testing and data than the traditional lens design in order to establish safety and effectiveness. Some finishing labs have assumed—incorrectly—that once the RGP lens material has been cleared for marketing by FDA, they may promote orthokeratology lens designs made with that material. This is an illegal practice.

## **Misunderstandings about Custom Devices**

Some companies that illegally market contact lenses have asserted that they are exempt from FDA regulation because, they claim, they are making "custom devices." This is an incorrect interpretation of FDA regulations; the agency has not considered tinted or orthokeratology contact lenses to be custom devices as defined in 812.3(b) of the Federal Food, Drug, and Cosmetic Act.

We have decided to use enforcement discretion in our approach to manufacturers of theatrical (or special effects) tinted lenses, provided the lenses are made for specified individuals for a single function—for example, a specific character in a specific movie. However, this discretion does not include manufacturers

that promote the sale of similar tinted lenses to the general public. To date, only two manufacturers have received FDA approval to market theatrical tinted lenses.

A licensed practitioner may individually design and prescribe an RGP orthokeratology lens for a particular patient within the scope of his/her practice. However, eyecare practitioners who promote orthokeratology in their practice should avoid making exaggerated and unsupported claims of safety or effectiveness. Promotional material should include accurate, well-balanced statements explaining that the effect of these lenses is temporary and limited. While we have decided to not intervene in this practice at the present time, we do reserve the authority to take future action if data become available that demonstrate an increased risk to public health associated with overnight use of orthokeratology lenses.

### **Reporting Adverse Events and/or Complaints**

We are asking for your help in identifying complaints or injuries associated with use of tinted or orthokeratology contact lenses. If an adverse event, problem and/or complaint is observed, we request that you report it directly to MedWatch, the FDA's voluntary reporting program, by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane (HF-2), Rockville, MD 20850.

### **Getting More Information**

Should you have questions about any of the items discussed in this letter, please contact James F. Saviola, O.D., F.A.A.O., CDRH, Office of Device Evaluation, HFZ-460, 9200 Corporate Blvd., Rockville, MD 20850 or FAX 301-480-4201.

Additional copies of this Advisory can be found on the FDA webpage at [www.fda.gov/cdrh/safety.html](http://www.fda.gov/cdrh/safety.html). If you are interested in receiving Safety Alerts, Public Health Advisories and other FDA medical device safety notices by e-mail when they are released, subscribe to our listserver. To subscribe, send an e-mail message to: [fdalists@archie.fda.gov](mailto:fdalists@archie.fda.gov). In the text of the e-mail, include: subscribe dev-alert.

Sincerely yours,

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